

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/EP2005/001441International filing date (day/month/year)
10.02.2005Priority date (day/month/year)
12.02.2004International Patent Classification (IPC) or both national classification and IPC
A61K31/454, A61P25/22Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b/s.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2005/001441

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☐ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☒ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2005/001441**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 2-7 (IA only)

Because:

- ☒ the said international application, or the said claims Nos. 2-7 (IA only) relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2005/001441

**Box No. V Reasoned statement under Rule 42bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-7 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-7 |
| Industrial applicability (IA) | Yes: Claims | 1 |
| | No: Claims | 2-7 |

2. Citations and explanations
see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/001441

1. Section II

The present application does not enjoy the claimed priority, since application GB0403149 of 12.02.2004 is not the first application where the present invention is disclosed. As a matter of fact application GB0308968 of 17.04.2003, which constitutes the priority document of document D1 (vide infra) already discloses (cf. in particular p. 10, I. 23; p. 10, II. 27-30; p. 12, II. 32-34; p. 17, II. 19-20; p. 18, Table 1; p. 18, II. 11-15) that 2-methoxy-5-(5-trifluoromethyl-tetrazol-1-yl-benzyl)-(2S-phenyl-piperidin-3S-yl)-amine is active in the gerbil social interaction model, and therefore in the treatment of social phobias. It is stressed that the document explicitly mentions that the single compounds of the composition are active, and the Table confirms this. It is concluded that GB0403149 is not the first application disclosing the present invention, and that therefore the presently claimed priority is invalid.

2. Section III

Claims 2-7 are directed to a method of treatment of the human/animal body by therapy. Such subject-matter is considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, and therefore no opinion shall be formulated with respect to industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT). However an opinion shall be formulated with respect to novelty and inventive step based on the alleged effects of the compounds/compositions.

3. Section V**3.1 Cited Documents**

The following documents (D) are referred to in this Opinion; the numbering will be adhered to in the rest of the procedure:

D1: WO 2004/091617 A (GLAXO GROUP LIMITED; MELOTTO, SERGIO) 28
October 2004 (2004-10-28)

Unless otherwise indicated reference is hereafter made to the passages cited in the Search Report

3.2 Art 33(2) PCT (Novelty)

The subject-matter of claims 1-7 the present application does not meet the requirements of

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/001441

Article 33(2) PCT.

WO 2004/091617 discloses that the presently claimed compound is active in the gerbil social interaction model, a model for anxiety and in particular for social phobia. It is therefore novelty-destroying for the present claims.

3.3 Art 33(3) PCT (Inventive step)

Since the question of the presence of an inventive step only arises when the subject-matter is new, a more detailed analysis of the compliance of the present application with the requirements of Art 33(3) PCT is postponed until the objections above are overcome, if at all.

3.4 Art 33(4) PCT (Industrial applicability)

As stated above, no opinion is given on the question of whether present claims 2-7 are industrially applicable since their patentability is *inter alia* dependent upon their formulation as well as upon national and regional laws and no unifying criteria is provided in this field by the PCT.